National Institutes of Health
National Cancer Institute

Division of Cancer Treatment and Diagnosis
Cancer Therapy Evaluation Program

Investigational Agent Trial
Letter of Intent

Please Print or Type

1. **Group/Institution(s):** _____

2. **Agent(s) to be supplied by NCI:** _____

3. **Other agents to be used in the protocol:** _____

4. **Tumor type:** _____

5. **Performance status:** _____

6. **Abnormal organ function permitted:** _____

7. **Prior therapy:** _____

8. **Phase of study:** _____

9. **Treatment** _____

10. **Rationale/hypothesis:** _____

11. **Laboratory correlates:** _____

12. Endpoints/Statistical considerations: _____

_____

_____

_____

_____

_____

_____

13. Proposed sample size: _____

14. Estimated annual accrual: _____

15. Projected accrual dates: **Beginning** _____ (month/year) **Ending** _____ (month/year)

16. Accrual documented by prior trials (similar tumor type/PS/prior Rx patients):

_____

17. List competing studies for which this patient population will be eligible:

_____

18. Consideration for contract credit is requested: **Yes** _____ **No** _____

_____ _____

Protocol Chair ***Date***

_____ _____

Group Chair/Contract PI (if applicable) ***Date***

Cooperative group LOIs must be submitted through the group operations office and must be appropriately signed. Proposals that will be submitted for contract credit through the IDB Phase I or Phase II/III contract mechanism must be signed by the principal investigator for the contract as well as the protocol chair.

LOIs should be submitted to: **LOI Coordinator**
Investigational Drug Branch
P. O. Box 30012
Bethesda, MD 20824
FAX: (301)402-5798